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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,202	11/12/2003	Randall J. Hucbner	ACM 352	8269
23581	7590	09/05/2007		
KOLISCH HARTWELL, P.C. 200 PACIFIC BUILDING 520 SW YAMHILL STREET PORTLAND, OR 97204			EXAMINER CUMBERLEDGE, JERRY L	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 09/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/712,202

Applicant(s)

HUEBNER ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9, 11, 13-15, 17-26, 28 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-9, 11, 13-15, 17-26, 28 and 31-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 5-9, 11, 13-15, 19, 21-25, 28, 31-33, 35-38 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Zahiri et al. (US Pat. 5,693,055).

Zahiri et al. disclose a method of compressing a bone, comprising: selecting a bone screw (Fig. 2, ref. 12) including a shank (Fig. 2, ref. 18) including a thread (Fig. 2, ref. 20) disposed externally (Fig. 2) for threaded engagement with bone (Fig. 1), the shank defining a long axis (Fig. 2) and a direction of advancement into bone (Fig. 2), and a head (Fig. 2, ref. 16) connected to the shank (Fig. 2) and defining a plurality of ledge structures (Fig. 2, ref. 24 and just below ref. 22) disposed at spaced positions along the head (Fig. 2), each ledge structure facing generally toward the direction of advancement (Fig. 1 and Fig. 2) and extending partially or completely around the head (Fig. 2) to define a respective plane disposed orthogonally to the long axis (Fig. 2); and installing the bone screw in a bone (Fig. 1) such that a portion of the bone near the head is engaged by one or more of the ledge structures (Fig. 1, ref. 24 engages bone) and is urged toward a portion of the bone near the shank (column 7, lines 22-30). The step of selecting a bone screw includes a step of selecting a bone screw in which the shank has a proximal portion (Fig. 2, portion near ref. 24) adjacent the head and a distal

portion (Fig. 2, portion near ref. 20) spaced from the head (Fig. 2), and wherein the thread is restricted to the distal portion (Fig. 2). The step of selecting a bone screw includes a step of selecting a bone screw that is self-tapping (Fig. 2). The step of selecting a bone screw includes a step of selecting a bone screw in which the shank includes a tip region configured to cut a hole in the bone as the bone screw is advanced into the bone (Fig. 2, ref. 20). The step of selecting a bone screw includes a step of selecting a bone screw in which the ledge structures are formed by a plurality of ridges (Fig. 2), a plurality of grooves, or both. The step of selecting a bone screw includes a step of selecting a bone screw in which one or more of the plurality of ledge structures extend in a closed loop corresponding to a circle (Fig. 2). The step of selecting a bone screw includes a step of selecting a bone screw in which the plurality of ledge structures have a corresponding plurality of diameters (Fig. 2), and wherein the diameters decrease successively toward the shank (Fig. 2). The step of selecting a bone screw includes a step of selecting a bone screw in which the head is shaped generally as a frustum of a cone, since the ledges give the screw head a generally conical shape (Fig. 2). The step of selecting a bone screw includes a step of selecting a bone screw in which the head includes a plurality of steps defined by stepwise decreases in the diameter of the head, and wherein the plurality of ledge structures are included in the plurality of steps (Fig. 2). The step of selecting a bone screw includes a step of selecting a bone screw in which the shank and the head define opposing ends of the bone screw (Fig. 2). The step of selecting a bone screw includes a step of selecting a bone screw in which the head and the shank are both part of the same monolithic structure (Fig. 2).

Zahiri et al. disclose a method of compressing bone screw for a bone, comprising: selecting a bone screw including a shank including a proximal region (Fig. 2, region near ref. 22), a distal region (Fig. 2, region near ref. 20), and a thread (Fig. 2, ref. 20) disposed externally for threaded engagement with bone and restricted to the distal region (Fig. 2), and a head (Fig. 2, ref. 16) connected to the shank and spaced from the thread by the proximal region, the head defining a plurality of spaced ledge structures (Fig. 2, ref. 24 and just below ref. 22) disposed generally along the head (Fig. 2), each ledge structure extending in a respective plane (Fig. 2) to describe at least an arc of a circle (Fig. 2) and installing the bone screw in a bone (Fig. 1) such that a portion of the bone near the head is engaged by one or more of the ledge structures (Fig. 1, ref. 24 engages bone) and is urged toward a portion of the bone near the shank (column 7, lines 22-30). The step of selecting a bone screw includes a step of selecting a bone screw in which the ledge structures describe complete circles (Fig. 2).

Zahiri et al. disclose a method of compressing a bone with a bone screw, comprising: forming a hole in the bone (column 6, lines 65-67); selecting a bone screw (Fig. 2, ref. 12) having a shank (Fig. 2, ref. 18) and a head (Fig. 2, ref. 16) connected to the shank (Fig. 2), the head defining a plurality of ledge structures (Fig. 2, ref. 24 and just below ref. 22) disposed at spaced positions generally along the head (Fig. 2), each ledge structure facing generally toward the direction of advancement (Fig. 2) and extending partially or completely around the head (Fig. 2) to define a respective plane disposed orthogonally to the long axis (Fig. 2); and advancing first the shank (Fig. 1, since the shank is inserted into the hole first) and then the head of the bone screw into

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the hole (Fig. 1) via threaded engagement of the shank (Fig. 1, near ref. 12) with the bone such that a portion of the bone near the head is engaged by one or more of the ledge structures (Fig. 1, ref. 24 engages bone) and is urged toward a portion of the bone near the shank (column 7, lines 22-30). The step of forming a hole includes a step of forming a bore (Fig. 1, bore which accepts ref. 12) and a counterbore (Fig. 1, bore which accepts ref. 14), and wherein the step of advancing disposes the head and the shank at least substantially in the counterbore and the bore, respectively (Fig. 1). The step of forming a hole is performed by the step of advancing (Fig. 1). The portion of the bone near the head and the portion of the bone near the shank are separated by a fracture in the bone (Fig. 1, ref. 6).

Zahiri et al. disclose a method of compressing a bone, comprising: selecting a bone screw (Fig. 2, ref. 12) including a shank (Fig. 2, ref. 18) including a thread (Fig. 2, ref. 20) disposed externally for threaded engagement with a bone (Fig. 1), the shank defining a long axis (Fig. 2) and a direction of advancement into bone (Fig. 1), and a head (Fig. 2, ref. 16) connected to the shank (Fig. 2) and including a plurality of spaced shoulders (Fig. 2, ref. 24 and just below ref. 22) of different diameter (Fig. 2), each shoulder facing generally in the direction of advancement (Fig. 1, Fig. 2) and extending partially or completely around the long axis (Fig. 2) in a respective path defining a plane (Fig. 2); and installing the bone screw in a bone (Fig. 1) such that a portion of the bone near the head is engaged by one or more of the shoulders (Fig. 1, ref. 24 engages bone) and is urged toward a portion of the bone near the shank (column 7, lines 22-30). The step of selecting a bone screw includes a step of selecting a bone screw in which

each shoulder follows a respective path defining a plane oriented orthogonally to the long axis (Fig. 2). The step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder follows a respective path corresponding to at least an arc of a circle (Fig. 2). The step of selecting a bone screw includes a step of selecting a bone screw in which each shoulder extends completely around the long axis in a closed loop (Fig. 2). The step of selecting a bone screw includes a step of selecting a bone screw in which the head includes at least one generally cylindrical segment disposed at least partially between a pair of the shoulders (Fig. 2, the cylindrical segment of ref. 24).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zahiri et al. (US Pat. 5,693,055).

Zahiri et al. disclose the claimed invention except for the aspect ratio being at least 1:1. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the aspect ratio of the device of Zahiri et al. being at least 1:1, since it has been held that where the general conditions of a claim

are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 34 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zahiri et al. (US Pat. 5,693,055) in view of Lahille et al (US Pat. 5,743,912).

Zahiri et al. disclose the claimed invention except for each shoulder/ledge sloping radially outward generally toward the direction of advancement into bone.

Lahille et al. disclose shoulders/ledges which slope radially outward (Fig. 5, ref. 14). This prevents the device from recoiling back out of the hole in which it is placed (column 5, lines 32-35).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the shoulders of Zahiri et al. with the radial outward slope as taught by Lahille et al., in order to prevent the device of Lombardo from recoiling back out of the hole in which it is placed (Lahille et al., column 5, lines 32-35).

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zahiri et al. (US Pat. 5,693,055) in view of Schenk (US Pat. 6,048,344).

Zahiri et al. disclose the claimed invention except for the head being rotatably and/or slidably connected to the shank.

Schenk discloses a device used in compression of bone fragments (Fig. 8, column 1, lines 8-12) which comprises a head (Fig. 4, ref. 1) which is slidably connected

(Figs. 7 and 8) to a shank (Fig. 4, ref. 60). This arrangement allows the head to provide improved compressive forces while permitting the bone screw head to be located beneath the bone surface (abstract).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the bone screw of Zahiri et al. with a head which is slidably connected to a shank as taught by Schenk, in order to allow the head of Zahiri et al. to provide improved compressive forces while permitting the bone screw head to be located beneath the bone surface (Schenk, abstract).

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zahiri et al. (US Pat. 5,693,055) in view of Ross et al. (US Pat. 5,470,334).

Zahiri et al. disclose the claimed invention except for an axial bore extending between the opposing ends; the axial bore includes a widened region configured to receive a tool that engages the head.

Ross et al disclose a bone screw (abstract) that comprises an axial bore (Fig. 1, ref. 50) that allows the screw to be placed over a guide wire (column 7, lines 10-13) and the axial bore including a region that is widened (Fig. 1 ref. 30), which allows for mating engagement with a driver (column 7, lines 13-16).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the bone screw of Zahiri et al. with an axial bore with a widened region as taught by Ross, which would allow a the screw to be

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placed over a guide wire (column 7, lines 10-13) and allow the screw to engage with a driver (column 7, lines 13-16).

Response to Arguments

Applicant's arguments with respect to claims 5-9, 11, 13-15, 17-26, 28 and 31-40, have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571)

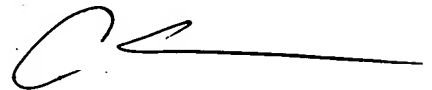
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272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



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